REMARKS

Claims 1, 2, 5-17 and 19-21 were examined and rejected. Claims 3, 4, and 18 stand withdrawn. Reexamination and reconsideration of pending claims 1, 2, 5-17, and 19-21 are respectfully requested.

Rejections under 35 U.S.C. §102(b)

In the Office Action, the Examiner rejected claims 1, 8-17 and 19-21 under 35 U.S.C. §102(b) as being anticipated by Hastings et al. (U.S. Patent No. 5,951,458). This rejection is respectfully traversed as follows.

Independent claim 1 recites a combined radiation and radiosensitizer delivery catheter comprising, in part, means for releasing a radiosensitizer to a body lumen. This element has not been reasonably shown or suggested by the cited art. The Examiner even concedes that Hastings et al. fails to disclose "a source of at least one radiosensitizer." Office Action dated June 4, 2003, page 5. As the Examiner knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131. The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

The Hastings et al. reference fails to teach means for releasing a radiosensitizer, much less a combined radiation and radiosensitizer delivery catheter to inhibit hyperplasia, as claimed by claim 1. Hastings et al. is instead directed toward a catheter that delivers oxidizing agents to blood vessel walls as a means of inhibiting restenosis. Specifically, Hastings et al. describes the use of hydrogen peroxides as the oxidizing agent. As the peroxide decomposes, hydroxyl ions are created which then damage, kill, or prevent the smooth muscle cells from multiplying thus significantly inhibiting restenosis (col. 17: 60-64). Radiation is then applied to further damage, kill or prevent smooth muscle cells from multiplying. In other words, radiation and the oxidizing agent work independently of one another in the prevention of restenosis. The peroxide does not increase the sensitivity of the tissue to radiation.

In stark contrast, the radiosensitizing agent of the present invention is used to increase the sensitivity of the tissue to the effects of radiation therapy. As clearly recited in claim 1, the radiation and radiosensitizing agent work together in combination to inhibit hyperplasia. Absent a showing in Hastings et al. for means for releasing a radiosensitizer, wherein the combined radiation and radiosensitizer delivery catheter inhibit hyperplasia, the present application is distinguished from the cited art and Applicants respectfully request withdrawal of this rejection and allowance of independent claim 1 (and dependent claims 2-21).

Rejections under 35 U.S.C. §102(e) and §102(f)

In the Office Action, the Examiner rejected claims 1-2 under 35 U.S.C. §102(e) and §102(f) as being anticipated by Forman et al. (U.S. Patent No. 6,390,967). Such rejections are respectfully traversed as follows.

As an initial matter, Applicants note that the Forman et al. patent is assigned to the assignee of the present application and represents earlier work of the assignee. Applicants concede that the Forman et al. patent teaches a radiation delivery catheter with shields. The present invention, however, teaches a hybrid treatment catheter of radiation and radiosensitizers to inhibit hyperplasia. In particular, independent claim 1 requires means for releasing a radiosensitizer, wherein the combined radiation and radiosensitizer delivery catheter inhibit hyperplasia. Applicants request that if the present rejection is maintained, the Examiner show or explain how the Forman et al. patent teaches such radiosensitizer limitations. Absent such a showing, Applicants respectfully request withdrawal of these rejections and allowance of independent claim 1 (and dependent claims 2-21).

Claim Rejection under 35 U.S.C. §103

In the Office Action, the Examiner rejected claim 2 under 35 U.S.C. §103(a) as being unpatentable over Hastings ('458) in view of Forman ('967). Claims 5-7 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Hastings ('458) or Forman ('967) in view of Tachibana et al. (U.S. Patent No. 6,176,842). Applicants note that the Forman et al. '967 patent qualifies as prior art only under 35 U.S.C. §102(e) and (f) as the '967 patent was filed on September 14, 2000 and issued on May 21, 2002 and the present application was filed on May 7,

2001. Moreover, the '967 patent and the present invention were, at the time the present invention was made, subject to an obligation of assignment to a common assignee, Xoft microTube, Inc. Hence, the present rejections can not preclude patentability under 35 U.S.C. §103(c). As such, Applicants respectfully request withdrawal of these rejections and allowance of these claims.

Double Patenting

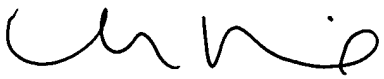
Claims 1-2, 5-17 and 19-21 were rejected under the judicially created doctrine of double patenting over claims 1-42 of U.S. Patent No. 6,537,195. To expedite prosecution of the present invention, Applicants file herewith a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c). Hence, the double patenting rejection is now moot.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415/ 576-0200.

Respectfully submitted,



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Attachments
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